UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: REVISED OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT REGARDING THE USE OF OXAMYL. (PC 103801 and DP Barcode D263856)

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Please find attached an occupational exposure and risk assessment for the use of oxamyl.

DP Barcode: D263856

Pesticide Chemical Codes: 103801

EPA Reg Nos: 352-372, 352-400, and 352-532

EPA MRID No.: 446869-01, 446869-02 and 447048-01

PHED: Yes, Version 1.1

Executive Summary

Oxamyl, [Methyl N', N'-dimethyl-N-[(methylcarbamoyl)oxy]-1-thio-oxamimidate], is an insecticide/nematicide. Oxamyl is formulated as a soluble concentrate/liquid (24% and 42% active ingredient) and as a solid/technical (42% active ingredient). Oxamyl is applied with the following equipment: groundboom sprayer, aerial equipment, airblast sprayer, chemigation, spotgun applicator, seed piece dip, and shank soil injection. Application rates for oxamyl range from 0.25 to 8 lb ai/acre.

Oxamyl is a restricted use pesticide. At this time, products containing oxamyl are intended for occupational use only. HED has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with oxamyl. Based on the use patterns of oxamyl, eight major exposure scenarios were identified for oxamyl: (1a) mixing/loading liquids for aerial application/chemigation; (1b) mixing/loading liquids for groundboom application; (1c) mixing/loading liquids for airblast application; (1d) mixing/loading liquids for spotgun applicator; (1e) mixing/loading liquids for high pressure handwand application; (2) applying liquids with aerial equipment; (3) applying liquids with a groundboom sprayer; (4) applying liquids with an airblast sprayer; (5) applying liquids for spotgun treatment; (6) Applying liquids with a high pressure handwand; (7) mixing/loading/applying liquids by seed piece dip; and (8) flagging for liquid aerial applications.

Calculations of risk based on combined dermal and inhalation exposure indicate that the MOEs are **more than <u>100</u>** with maximum risk reduction measures for all of the short and intermediate term occupational exposure scenarios listed above **except** for the following scenarios: applying liquids with a spotgun applicator; applying liquids with a high pressure handwand, mixing/loading liquids for aerial and application and chemigation for all application rates, and applying liquids with aerial equipment for all application rates. No data exists at this time to assess the scenario, mixing/loading/applying liquids by seed piece dip.

HED has determined that there are potential exposures to post-application workers during usual use-patterns associated with oxamyl. Three studies were submitted in support of the reregistration of oxamyl. The dislodgeable foliar residue (DFR) studies were done on three crops: cucumbers, tomatoes, and citrus fruits. Two sites were chosen for each crop one in California and one in Florida or Georgia, to represent an arid and a non-arid climate. A soil residue dissipation study was also done at the California site under tomato plants. For cucumbers, the calculated MOE exceeded the target MOE of 100 on day 4 for the California site and on day 1 for the Georgia site. For citrus trees, the calculated MOE exceeded the target MOE of 100 on day 3 for the Florida site and day 7 for the California site. For tomato foliage, the calculated MOE exceeded the target MOE of 100 on day 4 for the Florida site and day 3 for the California site.

<u>OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT FOR THE USE OF OXAMYL</u>

In this document, which is for EPA's development of the Oxamyl Reregistration Eligibility Decision Document (RED), HED presents the results of its occupational exposure and risk assessment for the use of oxamyl.

Use Patterns

Oxamyl is applied with the following equipment: groundboom sprayer, aerial eqiupment, airblast sprayer, chemigation, spotgun applicator, seed piece dip, and shank soil injection. Application rates for oxamyl range from 0.25 to 8 lb ai/acre.[1,2] Current oxamyl labels state that oxamyl can only be used in commercial and farm plantings. Oxamyl is not for use in home plantings, nor on any commercial crop that is turned into a "U-PICK" or "PICK YOUR OWN" or similar operation.[1]

Summary of Toxicity Concerns

Acute Toxicology Categories

Table 1 presents the acute toxicity categories as outlined in the *Oxamyl - Report of the Hazard Identification Assessment Review Committee*, dated August 31, 1999.[3]

Table 1. Toxicity Categories.

Study Type	Toxicity Category (technical)
Acute Oral Toxicity	I
Acute Dermal Toxicity	IV
Acute Inhalation Toxicity	II
Primary Eye Irritation	III
Primary Dermal Irritation	IV
Dermal Sensitization	Not a skin sensitizer

Toxicological Endpoints of Concern

The oxamyl endpoints were obtained from *Oxamyl - Report of the Hazard Identification Assessment Review Committee*, dated August 31, 1999 which indicates that there are toxicological endpoints of concern for oxamyl. Dermal and inhalation endpoints of concern have been identified for short-term (1 to 7 days) and intermediate-term (one week to several months) exposures.[3] These endpoints are listed in Table 2.

Table 2. Oxamyl Hazard Endpoints and Uncertainty Factors.

Route / Duration	NOAEL (mg/kg/day)	Effect	Study	Uncertainty Factors	Comments
Dermal (short and intermediate term)	50	Plasma, red blood cell and brain ChEI in females	21-Day Dermal Toxicity - Rabbit	Interspecies: 10x Intraspecies: 10x	
Inhalation (short and intermediate term)	0.1	Clinical signs, and decreased plasma, red cell and brain cholinesterase inhibition in females	Acute Neurotoxicity - Rat	Interspecies: 10x Intraspecies: 10x	100 percent lung absorption assumed.

The dermal and inhalation NOAELs were based on identical effects; therefore, the dermal and inhalation MOEs were combined in this risk assessment to determine a total MOE. No chronic scenarios were identified. The endpoints for both short and intermediate term dermal and short and intermediate term inhalation were identical. So, one total MOE to represent both the short and intermediate term was determined for each level of mitigation.

Summary of Use Pattern and Formulations

Occupational-Use and Homeowner-Use Products

Oxamyl, [Methyl N', N'-dimethyl-N-[(methylcarbamoyl)oxy]-1-thio-oxamimidate] is an insecticide/nematicide. Oxamyl is registered for use on terrestrial food crops and terrestrial food+feed crops.[1,2]

Type of Pesticide/Targeted Pest

Oxamyl is an insecticide and nematicide used only in commercial settings and includes (but, are not limited to) the following:[1]

- **Insects**: Pear Rust Mite, Citrus Rust Mite, European Rust Mite, McDaniel Spider Mite, Two spotted Spider Mite, Leafminer, Western Flower Thrips, Citrus Thrips, Onion Thrips, Flea Beetles, Colorado Potato Beetle, Pepper Weevil, Boll Weevil, Banana Root Borer, Carrot Weevil, Seperpentine Leafminer Complex, Vegetable Leafminer, Lygus Bugs, Tarnished Plant Bug, Cotton Fleahopper, Whiteflies, Cotton Aphid, Apple Aphid, Rosy Apple Aphid, Green Peach Aphid, Potato Leafhopper, White Apple Leafhopper, Pink Bollworm, Spotted Tentiform Leafminer, and Cotton Leaf Perforator;

- **Nematodes**: Stubby-root Nematode, Mint Nematode, Sting Nematode, Ring Nematode, Spiral Nematode, Lance Nematode, Reniform Nematode, Pin Nematode, Lesion Nematode, Root-Lesion Nematode, Burrowing Nematode, Bulb Nematode, Stem Nematode, Stunt Nematode, Citrus Nematode, Root-Knot Nematode, and Cyst Nematode;

- **Plant Regulator (Fruit Thinning).**

Formulation Types and Percent Active Ingredient

Oxamyl is formulated as a soluble concentrate/liquid (24% and 42% active ingredient) and as a solid/technical (42% active ingredient).[1]

Registered Use Sites[1,2]

Occupational-Use Sites

- **Food, Forage, Feed and Fiber Crops:** ginger, cantaloupes, yams, bananas, plantains, honeydew, watermelon, cucumbers, pumpkin, eggplant, peppers, pineapple, tomatoes, carrots, garlic, dry onions, potato, sweet potato, tobacco, celery, cotton, mint, peanuts, and soybeans.

- **Trees Crops:** non-bearing fruit trees (apple, cherry, citrus, peach and pear) and bearing-fruit trees (apples, citrus and pear).

- All ornamental and nursery uses have been canceled.

Application Rates[1,2]

The crop groupings with their corresponding maximum application rate are as follows:

- **Food, Forage, Feed and Fiber Crops:** Maximum application (foliar and/or soil sprays) rates are 1 lb ai/acre for cotton, and peppers, 2 lbs ai/acre for apples, eggplant, pears, yams, bananas, plantains, tobacco, tomatoes; 3 lbs ai/acre for mint and peanuts; 4 lbs ai/acre for celery, cucurbits (cucumbers, cantaloupe, honeydew, watermelon, squash, and pumpkin), garlic, onions, ginger, pineapple, potatoes, and soybeans; 6 lbs ai/acre for sweet potatoes, and 8 lbs ai/acre for carrots.

- **Tree Crops:** For soil directed application, the maximum application rate is 8 lbs ai/acre for non-bearing trees and for foliar application, the maximum application rate is 2 lbs ai/acre for non-bearing trees, apples, and pears, and 1 lb ai/acre for citrus.

Method and Types of Equipment Used for Mixing, Loading and Application[1,2]

- **Food, Forage, Feed and Fiber Crops:** Equipment for commercial use includes: groundboom, chemigation, aerial, shank injection (celery and tomatoes only), spotgun applicator (bananas and plantains in Puerto Rico only), and seed dip (yams in Puerto Rico only).

- **Tree Crops:** Equipment for commercial use includes: airblast, chemigation, aerial, high pressure handwand and ground boom (for pre-emergent use).

Timing and Frequency of Application

Oxamyl can be applied anywhere from 1 to 12 times a year depending on the crop. Most crops have a maximum seasonal application rate of 6 times or less.

OCCUPATIONAL EXPOSURE AND RISKS

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted to the Agency in support of the reregistration of oxamyl. It is the policy of the HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.[4]

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates)

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (i.e. mixing/loading, applying), formulation type (i.e. soluble concentrate), application method (i.e., groundboom sprayer), and clothing scenarios (i.e., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (i.e., chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table 6. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.[5]

Handler Exposures & Assumptions

HED has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with oxamyl. Based on the registered use patterns, eight major exposure scenarios were identified for oxamyl: (1a) mixing/loading liquids for aerial application/chemigation; (1b) mixing/loading liquids for groundboom application; (1c) mixing/loading liquids for airblast application; (1d) mixing/loading liquids with spotgun applicator; (1e) mixing/loading liquids for high pressure handwand; (2) applying liquids with aerial equipment; (3) applying liquids with a groundboom sprayer; (4) applying liquids with an airblast sprayer; (5) applying liquids for spotgun treatment; (6) applying liquids with a high pressure handwand; (7) mixing/loading/applying liquids by seed piece dip; and (8) flagging for liquid aerial applications.

The PPE required for handlers by current oxamyl labels includes: coveralls over short sleeved shirt and short pants, chemical resistant gloves, such as barrier laminate, butyl rubber, neoprene rubber, polyvinyl chloride, viton or nitrile gloves, chemical resistant footwear plus socks, protective eye wear, chemical resistant head wear for overhead exposure, chemical resistant apron when cleaning equipment, mixing or loading, and a respirator with an organic vapor cartridge with a pre-filter approved for pesticides, a canister approved for pesticides, or a NIOSH approved respirator with an organic vapor cartridge or canister with any R, P, or HE pre-filter.[1] The engineering control required for handlers by current oxamyl labels is the use of an enclosed cab for human flaggers.

Short-term and intermediate-term exposures and doses at baseline (developed using PHED Version 1.1 surrogate data) are presented in Table 3. The short- and intermediate-term MOEs with mitigation methods to handlers are presented in Table 4 and Table 5. The short and intermediate term dermal and inhalation MOEs are identical since they have the same endpoints. Table 6 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

The following general assumptions are made:

- Average body weight of an adult handler is 70 kg.
- Average work day interval is 8 hours which represents the acres treated or volume of spray solution prepared in a typical day.
- Calculations of handler scenarios are completed using the maximum application rates on the available oxamyl labels.
- PHED Version 1.1 data were used for to estimate exposures for all scenarios.[5]
- Due to a lack of scenario-specific data, HED calculated unit exposure values using generic data from the Pesticide Handler Exposure Database (PHED) and, in lieu of PHED data for a scenario, using protection factors that are applied to represent various risk mitigation options (i.e., the use of PPE and engineering controls).
- Exposures were estimated for handlers using 1200 acres per day for aerial equipment and chemigation on cotton, since it is a large acre crop, 350 acres for cotton flaggers, and 350 acres

per day for aerial equipment, flaggers, and chemigation on field and tree crops, 40 acres per day for airblast sprayers on tree crops, 1000 gallons for a high pressure handwand and 1 acre per day for a spotgun applicator. For groundboom equipment use on cotton, since it is a large acre crop, a range of 200 acres per day (upper-end estimate) to 80 acres per day (typical estimate) was used. For all other groundboom equipment uses, 80 acres per day was used.[10]

- Exposure from shank injection application on tomatoes and celery is considered to be similar to groundboom applicator exposure (scenario 4), therefore the shank injection application method was assessed under the groundboom scenario. This is a conservative estimate of the exposure since the application rates are lower, acres treated per day is lower and the spray is released in-ground.

Handler Equations

Potential daily dermal exposure is calculated using the following formula:

$$Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{day}\right) = Unit\ Exposure\left(\frac{mg\ ai}{lb\ ai}\right)\ x\ Use\ Rate\left(\frac{lb\ ai}{A}\right)\ x\ Daily\ Acres\ Treated\left(\frac{A}{day}\right)$$

Potential daily inhalation exposure is calculated using the following formula:

$$Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right) =$$
$$Unit\ Exposure\left(\frac{g\ ai}{lb\ ai}\right)\ x\ Conversion\ Factor\left(\frac{1mg}{1{,}000\quad g}\right)\ x\ Use\ Rate\left(\frac{lb\ ai}{A}\right)\ x\ Daily\ Acres\ Treated\left(\frac{A}{day}\right)$$

The daily dermal and inhalation dose is calculated using a 70 kg body weight for both short-term and intermediate-term exposure as follows:

$$Daily\ Inhalation\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right)\ x\left(\frac{1}{Body\ Weight\ (kg)}\right)$$

$$Daily\ Dermal\ Dose\left(\frac{mg\ ai}{Kg/Day}\right) = Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{Day}\right)\ x\left(\frac{1}{Body\ Weight\ (Kg)}\right)$$

The short-term and intermediate-term MOE for dermal exposure were calculated using a NOAEL of 50 mg/kg/day. The short-term and intermediate-term MOE for inhalation exposure was calculated using a NOAEL of 0.1 mg/kg/day. The inhalation and dermal MOEs were calculated using the following formulas:

$$Dermal\ MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Dermal\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

$$Inhalation\ MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Inhalation\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

Based on the available toxicity data, it is appropriate to combine short and intermediate term dermal and inhalation MOEs because the effects observed at the LOAEL were identical. The total MOE were calculated using the following formula:

$$Total\ MOE = \frac{1}{\left(\frac{1}{dermal\ MOE}\right) \quad \left(\frac{1}{inhalation\ MOE}\right)}$$

Table 3. Occupational Short-Term and Intermediate-Term Dermal and Inhalation Oxamyl Doses and Risk at Baseline.

Exposure Scenario (Scenario #)	Dermal Unit Exposure (mg/lb ai)[a]	Inhalation Unit Exposure (g/lb ai)[b]	Application Rate (lb ai/acre)[c]	Crop[d]	Daily Acres Treated[e]	Dermal Dose (mg/kg/day)[f]	Inhalation Dose (mg/kg/day)[g]	Dermal MOE[h]	Inhalation MOE[i]	Total MOE[j]
Loader Exposure and Dose Levels										
Mixing/loading liquids for aerial application/chemigation (1a)	2.9	1.2	1	cotton	1200	50	0.021	1	5	0.8
			3	mint	350	44	0.018	1	6	1
			4	pineapples	350	58	0.024	0.7	4	0.7
Mixing/loading liquids for airblast application (1b)			2	citrus	40	3	0.0014	15	73	13
Mixing/loading liquids for groundboom application (1c)			1	cotton	80	3.3	0.0014	15	73	13
					200	8	0.0034	6	29	5
			4	celery	80	13	0.0055	4	18	3
			8	carrots		27	0.011	2	9	2
Mixing/loading liquids for spotgun applicator (1d)			2	bananas/plantain	1	0.083	0.000034	600	2,900	500
Mixing/loading liquids for high pressure handwand (1e)			0.02 lbs ai/gal	pears	1000 gal/day	0.83	0.00034	60	290	50
Applicator Exposure and Dose Levels										
Applying Liquids with aerial equipment (2)	see eng. controls	see eng. controls	1	cotton	1200	see eng. controls	see eng. controls	see eng. controls	see eng. controls	see eng. controls
			3	mint	350	see eng. controls	see eng. controls	see eng. controls	see eng. controls	see eng. controls
Applying liquids with airblast equipment (3)	0.36	4.5	2	citrus	40	0.41	0.005	120	19	17
Applying liquids with groundboom sprayer (4)	0.014	0.74	1	cotton	80	0.01	0.0008	4400	120	120
					200	0.04	0.002	1300	47	16
			4	celery	80	0.06	0.003	780	30	28
			8	carrots		0.13	0.007	390	15	14

Exposure Scenario (Scenario #)	Dermal Unit Exposure (mg/lb ai)[a]	Inhalation Unit Exposure (g/lb ai)[b]	Application Rate (lb ai/acre)[c]	Crop[d]	Daily Acres Treated[e]	Dermal Dose (mg/kg/day)[f]	Inhalation Dose (mg/kg/day)[g]	Dermal MOE[h]	Inhalation MOE[i]	Total MOE[j]
Applying liquids with a spotgun applicator (5)	45.1	140	2	banana/plantain	1	1	0.004	39	25	15
Applying liquids with a high pressure handwand (6)	1.8	79	0.02 lbs ai/1000 gal	pears	1000 gal	0.51	0.023	97	4.4	4
Mixer/Loader/Applicator Exposure and Dose Levels										
Mixing/loading/applying liquid by seed piece dip (7)	no data	no data	2 lb ai/ 100 gallon	yams	no data	no data	no data	no data	no data	no data
Flagger Exposure										
Flagging liquid applications (8)	0.01	0.35	1	cotton	350	0.06	0.0018	910	57	54
			3	cucurbits	350	0.2	0.0053	300	19	18

Footnotes

a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor.
b Baseline inhalation exposure represents no respirator.
c Application rates are maximum application rates from the labels.
d Crops listed represent a group of crops with a similar application rate and application method.

Crop listed (max. app. rate (lbs ai/acre))	Also represents (max. app. rate (lbs ai/acre))
aerial/chemigation	
cotton (1)	white potatoes, celery, peppers, and peanuts (1), citrus, apples, pears (chemigation only), eggplant, tomatoes, and yams (2).
mint (3)	none
pineapples (4 - chemigation only)	none
airblast	
citrus (2)	apples, non-bearing trees and pears (2).
groundboom	
cotton (1)	peppers (1), eggplant, tobacco, yam and tomatoes (2).
celery (4)	mint and peanuts (3), cucurbits, garlic, onions, ginger, soybeans, pineapple, and white potato (4).
carrots (8)	sweet potato (6) and non-bearing trees (8).
high pressure handwand	
pears (0.02 lbs ai/gallon)	citrus and non-bearing trees (0.01 lbs ai/gallon).

e Daily acres treated are based on Science Advisory Council for Exposure Policy # 9.[10]
f Baseline Dermal Dose (mg/kg/day) = (Dermal Unit Exposure (mg/lb ai) * Application rate (lb ai/acre) * Acres treated (acres/day)) / Body weight (70 kg).
g Baseline Inhalation Dose (mg/kg/day) = (Inhalation Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion factor * Application rate (lb ai/A) * Acres treated (acres/day)) / Body weight (70 kg).
h Dermal MOE = Dermal NOAEL (50 mg/kg/day)/Short Term Dermal Dose (mg/kg/day).
i Inhalation MOE = Inhalation NOAEL (0.1 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).
j Total Intermediate-term MOE = 1/((1/Dermal MOE) + (1/ Inhalation MOE)).

Table 4. Occupational Short-Term and Intermediate-Term Dermal and Inhalation Exposure to Oxamyl and Doses with Additional PPE.

Exposure Scenario (Scenario #)	Crop[a]	Dermal Unit Exposure (mg/lb ai)[b]	Dermal Dose (mg/kg/day)[c]	Inhalation Unit Exposure (g/lb ai)[d]	Inhalation Dose (mg/kg/day)[e]	Dermal MOE[f]	Inhalation MOE[g]	Total MOE[h]
Loader Exposure and Dose Levels								
Mixing/loading liquids for aerial application/chemigation (1a)	cotton	0.017	0.29	0.12	0.0021	170	49	38
	mint		0.26		0.0018	200	56	43
	pineapples		0.34		0.0024	150	42	32
Mixing/loading liquids for airblast application (1b)	citrus		0.019		0.00014	2,600	730	570
Mixing/loading liquids for groundboom application (1c)	cotton- 80 acres		0.019		0.00014	2,600	730	570
	cotton - 200 acres		0.049		0.00034	1,000	290	230
	celery		0.078		0.00055	640	180	140
	carrots		0.16		0.0011	320	91	71
Mixing/loading liquids for spotgun treatment (1d)	Bananas/plantains		0.00049		0.0000034	-	-	-
Mixing/loading liquids for high pressure handwand (1e)	pears		0.0049		0.00003	10,000	2,900	2,300
Applicator Exposure and Dose Levels								
Applying Liquids with aerial equipment (2)	cotton	see eng. controls	see eng. controls	see eng. controls	see eng. controls	see eng. controls	see eng. controls	see eng. controls
	mint							
Applying liquids with airblast equipment (3)	citrus	0.22	0.25	0.45	0.00051	200	190	98
Applying liquids with groundboom sprayer (4)	cotton - 80 acres	0.011	0.013	0.074	0.00008	-	-	-
	cotton - 200 acres		0.031		0.00021	1,600	470	370
	celery		0.05		0.00034	1,000	300	230
	carrots		0.10		0.00068	500	150	110
Applying liquids with a spotgun applicator (5)	banana/plantain	20.6	0.59	14	0.0004	85	250	63

Exposure Scenario (Scenario #)	Crop[a]	Dermal Unit Exposure (mg/lb ai)[b]	Dermal Dose (mg/kg/day)[c]	Inhalation Unit Exposure (g/lb ai)[d]	Inhalation Dose (mg/kg/day)[e]	Dermal MOE[f]	Inhalation MOE[g]	Total MOE[h]
Applying liquids with a high pressure handwand (6)	pears	0.36	0.10	7.9	0.0023	490	44	41
Mixer/Loader/Applicator Exposure and Dose Levels								
Mixing/loading/applying liquid by seed piece dip (7)	yams	no data	no data	no data	no data	no data	no data	no data
Flagger Exposure								
Flagging liquid applications (8)	cotton	0.010	0.05	0.035	0.00018	1000	570	360
	mint		0.15		0.00053	330	190	120

Footnotes

a Crops listed represent a group of .crops with a similar application rate and application method.
b Additional PPE for all dermal scenarios includes double layer of clothing (50% Protection Factor for clothing) and chemical resistant gloves (90% Protection Factor).
c Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (60 kg)) .
d Additional PPE for all inhalation scenarios includes a organic vapor respirator (90% protection factor).
e Daily Inhalation Dose = ((Inhalation Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)* (1/1000)) / Body Weight (70 kg)) .
f Dermal MOE =Dermal NOAEL (50 mg/kg/day)/ Dermal Dose (mg/kg/day).
g Inhalation MOE = Inhalation NOAEL (0.1 mg/kg/day)/ Inhalation Dose (mg/kg/day).
h Total Intermediate-term MOE = 1/((1/Dermal MOE) + (1/ Inhalation MOE)).
S Calculated MOEs are below HED's level of concern at the previous level of mitigation. (total MOE 100).

Table 5. Occupational Short-Term and Intermediate-Term Dermal and Inhalation Exposure to Oxamyl and Doses with Engineering Controls.

Exposure Scenario (Scenario #)	Crop[a]	Dermal Unit Exposure (mg/lb ai)[b]	Dermal Dose (mg/kg/day)[c]	Inhalation Unit Exposure (g/lb ai)[b]	Inhalation Dose (mg/kg/day)[d]	Dermal MOE[e]	Inhalation MOE[f]	Total MOE[g]
Loader Exposure and Dose Levels								
Mixing/loading liquids for aerial application/chemigation (1a)	cotton	0.0086	0.15	0.083	0.0014	340	70	58
	mint		0.14		0.0013	370	80	66
	pineapples		0.17		0.0017	300	60	50
Mixing/loading liquids for airblast application (1b)	citrus		0.01		0.00009			
Mixing/loading liquids for groundboom application (1c)	cotton - 80 acres		0.010		0.00009	-	-	-
	cotton - 200 acres		0.025		0.00024			
	celery		0.039		0.00038			
	carrots		0.079		0.00076	640	130	110
Mixing/loading liquids for spotgun treatment (1d)	Bananas/plantains		0.00025		0.0000024	-	-	-
Mixing/loading liquids for high pressure handwands (1e)	Pears		0.0026		0.000024	-	-	-
Applicator Exposure and Dose Levels								
Applying Liquids with aerial equipment (2)	cotton	0.005	0.086	0.068	0.0012	580	86	75
	mint		0.075		0.0010	670	98	85
Applying liquids with airblast equipment (3)	citrus	0.019	0.022	0.45	0.00051	2,300	190	180
Applying liquids with groundboom sprayer (4)	cotton - 80 acres	0.005	0.006	0.043	0.00005	-	-	-
	cotton - 200 acres		0.014		0.00012			
	celery		0.023		0.00020			
	carrots		0.046		0.00039			
Applying liquids with a spotgun applicator (5)	banana/plantain	NA	NA	NA	NA	NA	NA	NA

Exposure Scenario (Scenario #)	Crop[a]	Dermal Unit Exposure (mg/lb ai)[b]	Dermal Dose (mg/kg/day)[c]	Inhalation Unit Exposure (g/lb ai)[b]	Inhalation Dose (mg/kg/day)[d]	Dermal MOE[e]	Inhalation MOE[f]	Total MOE[g]
Applying liquids with a high pressure handwand (6)	pears	NA	NA	NA	NA	NA	NA	NA
Mixer/Loader/Applicator Exposure and Dose Levels								
Mixing/loading/applying liquid by seed piece dip (7)	yams	NA	NA	NA	NA	NA	NA	NA
Flagger Exposure								
Flagging liquid applications (8)	cotton	0.00022	0.0011	0.007	0.00004			
	mint		0.0033		0.00011	-	-	-

Footnotes

a Crops listed represent a group of crops with a similar application rate and application method.

b Scenario Number — Engineering Controls
- 1a / 1b/1c — Closed mixing / loading, single layer clothing, chemical resistant gloves.
- 2, 3, 4, 8 — Enclosed cab, cockpit, truck (98% protection factor)., single layer clothing, no gloves.

c Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (60 kg)) .

d Daily Inhalation Dose = ((Inhalation Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)* (1/1000)) / Body Weight (70 kg)) .

e Dermal MOE =Dermal NOAEL (50 mg/kg/day)/ Dermal Dose (mg/kg/day).

f Inhalation MOE = Inhalation NOAEL (0.1 mg/kg/day)/ Inhalation Dose (mg/kg/day).

g Total Intermediate-term MOE = 1/((1/Dermal MOE) + (1/ Inhalation MOE)).

NA Not Applicable-the Agency does not consider engineering controls an effective approach for mitigating exposures during the use of certain types of equipment.

S Calculated MOEs are below HED's level of concern at the previous level of mitigation. (total MOE 100).

Table 6. Occupational Exposure Scenario Descriptions for the Use of Oxamyl.

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Exposure			
Mixing/Loading Liquid Formulations (1 a /1b/1c/1d/1e)	PHED V1.1	1200, 350 acres for aerial and 200, 80 acres for groundboom, 40 for airblast, 1 acre for spotgun applicator, 1000 gallons for high pressure handwand.	**Baseline:** Hands, dermal, and inhalation AB grades. Dermal = 75 to 122 replicates; hands = 53 replicates; and inhalation= 85 replicates. High confidence in all data. **PPE:** Hands, dermal, and inhalation = AB grades. Dermal = 75 to 122 replicates; hands = 59 replicates; and inhalation = 85 replicates. High confidence in all data. **Engineering Controls:** Hands, dermal, and inhalation = AB grades; Dermal = 16 to 22 replicates; hands = 31 replicates; and inhalation = 27 replicates. High confidence in all data. PHED data were used for baseline, no protection factors (PFs) were necessary. A 50% PF was added to simulate coveralls for PPE. An 90% PF was used for PPE for inhalation to represent a organic vapor respirator. Engineering Controls data were monitored with chemical resistant gloves.
Applicator Exposure			
Applying Liquids with Aerial Equipment (2)	PHED V1.1	1200, 350 acres	**Engineering controls:** Dermal and inhalation = ABC grades; and hands = AB. Dermal = 24 to 48 replicates; hands = 34 replicates; and inhalation = 23 replicates. Medium confidence in all data.
Applying Liquids with an Airblast Sprayer (3)	PHED V1.1	40 acres	**Baseline:** Hands, dermal, and inhalation = AB grades. Dermal = 32 to 49 replicates; hands = 22 replicates; and inhalation = 47 replicates. High confidence in all data. **PPE:** Hands, dermal, and inhalation = AB grades. Dermal = 31 to 48 replicates; hands = 18 replicates; and inhalation = 47 replicates. High confidence in all data. **Engineering Controls:** Hands and dermal =AB grades; and inhalation= ABC grades. Dermal = 20 to 30 replicates; hands = 20 replicates; and inhalation = 9 grades. High confidence in dermal data. Low confidence in inhalation data. A 50 percent PF was used for PPE to simulate coveralls. Engineering Controls data were monitored with chemical resistant gloves. 90% PF for the addition of a organic vapor respirator.
Applying liquids by Groundboom Application (4)	PHED V1.1	200, 80 acres	**Baseline:** Hands and dermal, and inhalation = AB grades. Dermal = 23 to 42 replicates; hands = 29 replicates; and inhalation = 22 replicates. High confidence in all data. **PPE:** Dermal and inhalation = AB grades; hands = ABC grades. Dermal = 23 to 42 replicates; hands = 21 replicates; and inhalation= 22 replicates. Medium confidence in dermal and hands data. High confidence in inhalation data. **Engineering Controls:** Dermal and hands = ABC grades. Dermal = 20 to 31 replicates; hands = 16 replicates. Medium confidence in dermal and hands data. High confidence in inhalation data. PHED data were used for baseline, no PFs were necessary. A 50% PF was added to the PPE scenario to simulate coveralls. 90% for the addition of a organic vapor respirator.

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Applying liquids by Spotgun Application (5)	PHED Study # 0457 (waved into PHED but not incorporated, see upcoming version 2.0)	1 acre	**Baseline:** Hands, dermal, and inhalation = B grade. Dermal = 15 replicates; hands = 15 replicates; and inhalation = 15 replicates. High confidence in all data. **PPE:** Hands, dermal, and inhalation = B grade. Dermal = 15 replicates; hands = 15 replicates; and inhalation = 15 replicates. High confidence in all data. A 50% PF was added to the PPE scenario to simulate coveralls. 90% for the addition of a organic vapor respirator.
Applying liquids with a high pressure handwand (6)	PHED V1.1	1000 gallons	**Baseline:** Hand, dermal, and inhalation data are all grades. Hand = 2 replicates; dermal = 9 to 11 replicates; and inhalation = 11 replicates. Low confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure value. **PPE:** Hand/dermal data are all grades. The same inhalation data are used as for the baseline coupled with an 90% protection factor to account for the use of a organic vapor respirator. Hand = 9 replicates and dermal = 9 to 11 replicates. Low confidence in hand/dermal data. **Engineering Controls:** Not feasible for this scenario. A 50% PF was added to the PPE scenario to simulate coveralls. 90% for the addition of a organic vapor respirator.
Mixer/Loader/Applicator Exposure and Dose Levels			
Mixing/loading/applying liquids for Seed Piece Dip (7)	no data	no data	no data
Flagger Exposure			
Flagging Aerial Spray Applications (8)	PHED V1.1	350 acres	**Baseline:** Hands, dermal, and inhalation = AB grades. Hands = 30 replicates; dermal = 17 to 57 replicates; and inhalation = 28 replicates. High confidence in dermal, hands, and inhalation data. **PPE:** Hands, dermal, and inhalation = AB grades. Hands = 6 replicates; dermal = 18 to 28 replicates; and inhalation = 28 replicates. High confidence in dermal and inhalation data. Low confidence in hands data. **Engineering Controls:** Same as baseline. PHED data were used for baseline, no PFs were necessary. A 50% PF was added for PPE to represent coveralls. 90% PF for addition of a organic vapor respirator. A 98 percent PF was applied to baseline to simulate engineering controls.

Footnotes

[a] Standard Assumptions based on an 8-hour work day as estimated by EPA. BEAD data were not available.

[b] "Best Available" grades are defined by EPA SOP for meeting Subdivision U Guidelines. Acceptable grades are matrices with grades A and B data. Data confidence are assigned as follows:

High	= grades A and B and 15 or more replicates
Medium	= grades A, B, and C and 15 or more replicates
Low	= grades A, B, C, D, and E <u>or</u> any combination of grades with less than 15 replicates

Summary of Risk Concerns for Occupational Handlers

The target MOE for all scenarios is 100. The short and intermediate-term dermal and inhalation NOAELs were based on identical endpoints, the MOEs were combined to identify a total MOE.

Baseline Level

All calculated short- and intermediate-term total MOEs were **less than** 100 at the **baseline** level **except** the following:

- (1d) Mixing/Loading liquids for spotgun applicator.
- (4) Applying liquids with a groundboom sprayer on cotton (1 lb ai/acre) at 80 acres per day.

Additional PPE

The calculations of short- and intermediate- term risk indicate that the total MOEs are **more than** 100 at the **additional PPE** level for all assessed exposure scenarios **except** the following:

- (1a) Mixing/Loading liquids for aerial and chemigation application for all application rates.
- (1c) Mixing/Loading liquids for groundboom application for the highest application of 8 lbs ai/acre.
- (3) Applying liquids with airblast equipment at all application rates.
- (5) Applying liquids with a spotgun applicator. (not able to mitigate with engineering controls)
- (6) Applying liquids with a high pressure handwands. (not able to mitigate with engineering controls)

Engineering Controls

The calculations of short- and intermediate- term risk indicate that the total MOEs are **more than** 100 at the **engineering control** level for all assessed exposure scenarios **except** the following:

- (1a) Mixing/Loading liquids for aerial and chemigation application for all application rates.

- (2) Applying liquids with aerial equipment for all application rates.

Data Needs

There were no available data to assess the exposure scenario mixing/loading/applying liquids by a seed piece dip (scenario 7).

Post Application Exposure Assessment:

The registrant has submitted three dislogeable foliar residue (DFR) studies in support of the reregistration of oxamyl:

- *"Dissipation of Dislodgeable Foliar Residues of Oxamyl From Citrus Following Application of Vydate® L Insecticide in the U.S.A - Season 1997"*; MRID 446869-01.

- *"Dissipation of Dislodgeable Foliar Residues of Oxamyl From Cucumbers Following Application of Vydate® L Insecticide in the U.S.A. - Season 1997."*; MRID 446869-02.

- *"Dissipation of Dislodgeable Foliar and Soil Residues of Oxamyl Following Application of Vydate® L Insecticide to Tomatoes in the USA- Season 1997 and 1998."*; MRID 447048-01.

The current oxamyl label re-entry interval (REI) is 48 hours. The PPE required on current oxamyl labels for early entry that involves contact with anything that has been treated, such as plants, soil or water, is: coveralls over short-sleeved shirt and short pants, chemical resistant gloves, such as barrier laminate, butyl rubber, neoprene rubber, polyvinyl chloride, viton or nitrile gloves, chemical resistant footwear plus socks, protective eye wear, and chemical resistant head wear for overhead exposure.

The dissipation data obtained from these studies has been used to determine the days after treatment when the calculated MOE was above the target MOE for all oxamyl crops. See Appendix 1 for the raw data from the 3 dissipation studies. The raw data from the studies are corrected for recoveries as appropriate. The data is then natural log transformed. A semi-log regression analysis is run on the log transformed data. From the regression analysis, a dissipation rate (slope) and predicted dislodgeable foliar residue data for each site and crop is determined. The following calculations are used to calculate the dose and MOE. The REI is established on the day that the calculated MOE is 100 or above.

Daily dose is calculated as follows:

$$Dose\ (mg/kg/d) = \frac{(DFR\ (\ g/cm^2)\ x\ Tc\ (cm^2/hr)\ x\ CF\left(\frac{1\ mg}{1{,}000\ \ g}\right)\ x\ ED\ (hrs)}{BW\ (kg)}$$

Where:

DFR	= Dislodgeable Foliar Residue initial or daily (g/cm^2) at time (t).
Tc	= Transfer coefficient (cm^2/hr)
CF	= Conversion factor (1 mg/1,000 g)
ED	= Exposure duration (hours per day)
BW	= Body weight (kg)

The daily MOE is calculated as follows:

$$MOE = \frac{NOEL \ (mg/kg/day)}{Dose \ (mg/kg/day)}$$

Where:
NOAEL = 50 mg/kg/day
Dose = Calculated dose

Assumptions

- The transfer coefficient used for exposure to curcubits, ginger, peanuts, cotton, pepper and eggplant foliage was 4,000 cm^2/hr for activities such as hand harvesting, late season scouting, staking/tying and irrigating.[6]

- The transfer coefficient used for exposure to celery and pineapple foliage was 2,500 cm^2/hr for activities such as hand harvesting.[6]

- The transfer coefficient used for exposure to citrus, pear, apple and non-bearing trees was 10,000 cm^2/hr for activities such as hand harvesting, transplanting and pruning.[6]

- The transfer coefficient used for exposure to tomatoes, yams, white potatoes, garlic and onions was 10,000 cm^2/hr for activities such as staking/tying, irrigating, hand harvesting and digging.[6]

- A route specific dermal study was used to select an endpoint, so a dermal absorption value is not necessary.

- The exposure duration is assumed to be 8 hour work day.

- Adult body weight is 70 kg.

Table 7 is a summary of the studies' parameters as well as the days after treatment when the calculated MOE is above the target MOE for quick comparison.

Table 7. Comparisons of Study Parameters.

Crop	Tomatoes			Citrus		Cucumbers	
Site	**Florida**	**California (foliage)**	**California (soil)**	**Florida**	**California**	**Georgia**	**California**
Day After Treatment	4	3	-	3	7	1	4
Transfer Coefficients (cm^2/hr)	10,000			10,000		4,000	
Actual Rainfall (inches)	14	0.05	0	14	1.3	12.6	0
Average Rainfall (inches)	5.2	0	0	20	1.5	15	0
Percent Dissipation (slope)	43	12	10	23	7.8	51	24.5
Initial Residues (g/cm^2)	4.1	7.1	29	3.1	2.3	4.1	3.9
Study Application Rate (lb ai/A)	1			1		1	
Label Max. Application Rate (lb ai/A)	1		2	1		1	
Half Life (days)	5.8	1.6	6.8	3.7	8.9	1.4	2.5
R^2 Values	0.99	0.67	0.8	0.85	0.76	0.81	0.94
PHI (days)	3			7		1	

Cucumbers

The study, *"Dissipation of Dislodgeable Foliar Residues of Oxamyl From Cucumbers Following Application of Vydate® L Insecticide in the U.S.A. - Season 1997."*; (MRID 446869-02), was submitted by the registrant and reviewed by HED. The study was conducted at two sites, one in California and one in Georgia, during the summer of 1997. The treated plot at each site received two applications of Vydate®L insecticide using a tractor mounted boom sprayer. There was a fourteen day interval between the applications. The application rate for each treatment was 1 pound of active ingredient (ai) per acre applied at a rate of 50 gallons per acre of finished spray at both sites. The data from leaf punches after the second treatment were used to characterize concentration of oxamyl on the treated crop and the rate of dissipation.

The subplots at the California site were furrow /flood irrigated, while the subplots at the Georgia site did not require irrigation. The rainfall for the month of July was 10.64 inches at the Georgia site. This exceeded the 10-year average for July at the Georgia site of 6.58 inches. However, the total average rainfall during the course of the study at the Georgia site was 12.55 inches. This was lower than the 10-year total average for the same stretch of time, which was 14.97 inches. At the California site, there was no rain during the course of the study and the irrigation water did not wet the sampled foliage.

Foliage leaf punch samples were collected randomly from dry viable leaves from each subplot and control plot using a one inch diameter Birkestrand® leaf punch sampler. One control sample from the control plot and three replicate samples from the treated plot were collected at both study sites at the following sampling intervals: prior to each application, immediately after each application after the spray dried (day 0), and 1, 2, 3, 7, 14 ,21, 28, and 35 days after the second (final) application. The California site experienced an insect infestation after the 28th day, leaving no viable leaves to be sampled on the 35th day.

The study report did not mention correcting DFR data for recovery results. After the second application, average reported DFR residues declined from 3.009 g/cm^2 on day 0 to 0.004 g/cm^2 on Day 28 at the CA site, and from 2.341   g/cm^2 on day 0 to less than the limit of quantitation (LOQ), 0.001   g/cm^2, on Day 21 at the GA site. The registrant reported the half-life of oxamyl on cucumber leaves as 2 days with the calculated R squared (R^2) value of 0.986 for the CA site, and 0.54 days with the R^2 of 0.986 for the GA site. Series 875 - Group B (formerly Subdivision K) guidelines require that DFR data be corrected if the recovery values are less than 90 percent. This correction was performed for both sites. The calculated half-life of oxamyl on cucumber leaves after correction was 2.46 days with the R^2 of 0.94 for the CA site, and 1.36 days with the R^2 of 0.81 for the GA site. Rainfall events occurred at the GA site may explain the reason why the half-life at the GA site was shorter than that at the CA site. The coefficient of variance (CV) for the corrected residues at each sampling interval ranged between 2.9 and 29.4 percent for the CA site and between 3.36 and 50 percent for the GA site. For the Georgia site, the actual DFR data on the day the calculated MOE was above the target MOE were above the predicted DFR values. Since using the predicted values for these days would underestimate exposure, the actual values were used instead for day 0 and 1 for this site. Results from the regression analysis are presented in Table 8 of this report.

Table 8. Predicted Cucumber Foliar Dissipation Values for Oxamyl - Based on Log Transformed Data.

DFR (g/cm^2) – (Values in Parentheses are Actual Field Measured Averages)										
Site	0 DAT	1 DAT	2 DAT	3 DAT	4 DAT	5 DAT	6 DAT	7 DAT	R^2	Slope ($t_{½}$ days)[a]
Georgia	(4.1)	(0.87)	0.36	0.22	0.31	0.079	0.048	0.029	0.81	-0.508 (1.36)
California	3.2	2.4	1.8	1.4	1.03	0.78	0.59	0.44	0.94	-0.282 (2.46)

a $t_{½}$ is the calculated half-life of oxamyl at the Georgia site are from 0 DAT to 14 DAT and the half-life of oxamyl at the California site are from 0 DAT to 28 DAT.

The dislodgeable foliar residue study completed in support of the regulatory requirements contained the following omissions and flaws with respect to Series 875 - Group B guidelines. However, the data collected in this study are of sufficient scientific quality.

- a storage stability study was not presented and is recommended because of the short half-life of the pesticide and poor recovery results.
- since the recovery data was less than 90 percent, the DFR data should have been corrected based on the recovery percentage.
- the results of the control samples were not provided in the study, so if any chemical interference took place in the control samples, it could not be determined.
- almost all of the recoveries for the Georgia site were below 70 percent.
- only two sites were addressed, but Series 875 - Group B guidelines recommends at least three sites.
- tank mix samples to verify the concentration of the spray solution prior to and after each application were not collected.

The field fortification recoveries should take into account any storage stability problems. The residue data were corrected for recoveries by HED. HED recognizes that two sites are not as representative of the entire country as the three sites required by the guidelines. The rest of the omissions or flaws with respect to the Series 875 - Group B guidelines are not considered to significantly affect the outcome of the data.

The assessment uses a transfer coefficient (Tc) for cucumbers of 4,000 cm^2/hr for activities such as hand harvesting, scouting and irrigating[6]. The actual initial residues were similar for both sites, but the residue at the Florida site dissipated at a higher rate. The dissipation rates were determined from the regression analysis to be 51 percent per day for the Georgia site and 28 percent per day for the California site. The R^2 value from the California site (0.99) was much higher than the Florida site (0.81). The DFR data were derived by correcting the raw data for recoveries, log transforming the data, and then running a regression analysis on the data. The predicted DFR data from the regression analysis were then used to obtain the dose for each day, except for the Georgia site on day 0 and 1. For the Georgia site, the actual DFR data on the day the calculated MOE was above the target MOE were above the predicted DFR values, so the actual values were used instead for day 0 and 1 for this site. The daily DFR, dose and MOE values for the California and Georgia sites are presented in Table 9.

Table 9. Oxamyl Surrogate Postapplication Assessment for Cucumbers.

DAT[a]	DFR (µg/cm^2)[b]		Dermal Dose (mg/kg/day)[c]		MOE[d]	
	GA	CA	GA	CA	GA	CA
0	(4.1)	3.2	1.9	1.5	27	34
1	(0.87)	2.4	0.40	1.1	130	46
4	NA	1.03	NA	0.47	NA	110

Footnotes
NA = Not applicable
[a] DAT is "days after treatment"
[b] Predicted DFR was obtained through study data of the insecticide residues on cucumber foliage[7]. The DFR data in parenthesis were actual measured data.
[c] Dose = DFR (g/cm^2) x Transfer coefficient (4,000 cm^2/hr) x Conversion factor (1mg/1000 g) x Dermal absorption (1) x Hrs worked per day (8 hrs) / Body weight (70 kg)
[d] MOE = NOAEL (mg/kg/day) / Dermal dose (mg/kg/day). Where: NOAEL is 50 mg/kg/day.

For cucumbers, the calculated MOE exceeded the target MOE of 100 on day 4 for the California site and on day 1 for the Georgia site.

Citrus

The study, *"Dissipation of Dislodgeable Foliar Residues of Oxamyl From Citrus Following Application of Vydate® L Insecticide in the U.S.A - Season 1997"* (MRID 446869-01) was submitted by the registrant and review by HED. The study was done at two sites, one in Florida and one in California. The treated plots at each site received two applications of Vydate®L insecticide using airblast sprayer applications of the test substance. At the California site, each application was 1.0 pounds of active ingredient per acre, in 100 gallons of finished spray per acre. The data from leaf punches after the second treatment were used to characterize concentration of oxamyl on the treated crop and the rate of dissipation. A protocol deviation occurred when the first application in Florida. Vydate®L sprayed 1.25 lb ai/acre due to an increase in spray pressure from 60 to 100 psi at 147 gallons per acre. Insertion of a pressure regulator for the second application brought the application rate down to 1.0 lb ai/acre, in 101 gallons of finished spray per acre. The sprayers were calibrated prior to all applications by the volume/time method. In California, irrigation occurred four times with a microsprinkler irrigation that did not wet the foliage sampled. The California site had 1.3 inches of rainfall during the course of the study, with a ten year average of 1.46 inches. In Florida, the rainfall per day ranged from 0.2 to 2.6 inches. The total rainfall during the sampling period was 13.7 inches, with a ten year average of 20 inches.

Since the DFR residue levels used for regression analysis were corrected based on recovery data, HED's calculated R^2 values and predicted half-lives were different from the values than were reported by the registrant for a first-order regression. HED's R^2 was 0.76 for DFR residue in California and 0.85 for DFR residue in Florida. The study report author calculated the California site R^2 value to be 0.58. The R^2 value should have been calculated for the Florida site; however, it has been omitted from the study report. HED calculated the half lives at 8.9 days for the California site and 3.1 days for the Florida site. The half-lives reported by the registrant were 3.3 days for California and 1.2 days for Florida. For the Florida site, the actual DFR data on the day when the calculated MOE was above the target MOE were above the predicted DFR values. Since using the predicted values for these days would underestimate exposure, the actual values were used instead for day 0,1 and 2 for this site. Results from HED's regression analysis are presented in Table 10 of this report.

Table 10. Predicted Citrus Foliar Dissipation Values for Oxamyl Based on Log Transformed Data.

DFR (g/cm^2) –(Values in Parentheses are Actual Field Measured Averages)										
Site	0 DAT	1 DAT	2 DAT	3 DAT	4 DAT	5 DAT	6 DAT	7 DAT	R^2	Slope ($t_{½}$ days)[a]
Florida	(2.1)	(1.44)	(0.47)	0.31	0.25	0.20	0.16	0.13	0.92	-0.498 (3.08)
California	0.739	0.683	0.632	0.585	0.541	0.501	0.463	0.429	0.76	-0.078 (8.92)

a $t_{½}$ is the calculated half-life of oxamyl at the Florida and California site are from 0 DAT to 35 DAT.

The dislodgeable foliar residue study completed in support of the regulatory requirements contained the following omissions and flaws with respect to Series 875 Group B Postapplication Exposure Monitoring Test Guidelines. However, the data collected in this study are of sufficient scientific quality.

- a storage stability study was not presented and is recommended due to the short half life of the pesticide and poor recovery in some of the samples.

- since the field recovery was less than 90 percent, the DFR data should have been corrected based on the field recovery percentage. HED corrected the data based on recoveries.

- sampling was performed at two geographically distinct locations, however, Series 875 Group B recommends testing at three sites.

- the results of the control samples were not reported in the study, so it could not be identified whether any chemical interference took place in the control samples.

- the sampling strategy was a non-directed approach rather than the Iwata approach which EPA recommends for tree crop.

The field fortification recoveries should take into account any storage stability problems. The residue data were corrected for recoveries by HED. HED recognizes that two sites are not as representative of the entire country as the three sites required by the guidelines. The rest of the omissions or flaws with respect to the Series 875 - Group B guidelines are not considered to significantly affect the outcome of the data.

The assessment uses a transfer coefficient (Tc) for citrus of 10,000 cm^2/hr for activities such as hand harvesting, and pruning[6]. The DFR data were derived by correcting the raw data for recoveries, log transforming the data, and then running a regression analysis on the data. The dissipation was determined from the regression analysis to be 23 percent per day for the Florida site and 7.8 percent per day for the California site. The R^2 squared value for the Florida site (0.92) was higher than the California site (0.76). The predicted DFR data from the regression analysis were then used to obtain the dose for each day, except for days 0, 1 and 2 at the Florida site. For the Florida site, the actual DFR data on the day that the calculated MOE was above the target MOE were above the predicted DFR values, so the actual values were used instead for day 0,1 and 2 for this site. The daily DFR, dose and MOE values are presented in Table 11.

Table 11. Oxamyl Surrogate Postapplication Assessment for Citrus.

DAT[a]	DFR (µg/cm^2)[b]		Dermal Dose (mg/kg/day)[c]		MOE[d]	
	FL	CA	FL	CA	FL	CA
0	(2.1)	0.74	2.4	0.84	21	60
3	0.31	0.59	0.35	0.67	140	75
7	NA	0.43	NA	0.49	NA	100

Footnotes
NA = Not applicable
[a] DAT is "days after treatment"
[b] Predicted DFR was obtained through study data of the insecticide residues on cucumber foliage. The DFR data in parenthesis were actual measured data[8].
[c] Dose = DFR (g/cm^2) x Transfer coefficient (10,000 cm^2/hr) x Conversion factor (1mg/1000 g) x Dermal absorption (1) x Hrs worked per day (8 hrs) / Body weight (70 kg)
[d] MOE = NOAEL (mg/kg/day) / Dermal dose (mg/kg/day). Where: NOAEL is 50 mg/kg/day.

For citrus trees, the calculated MOE exceeded the target MOE of 100 on day 3 for the Florida site and day 7 for the California site.

Tomatoes

The study, *"Dissipation of Dislodgeable Foliar and Soil Residues of Oxamyl Following Application of Vydate® L Insecticide to Tomatoes in the USA- Season 1997 and 1998."* (MRID 447048-01) was submitted by the registrant and reviewed by HED. There were two sites in the study, one in California and one in Florida. Two applications of Vydate®L, were applied 5 days apart to test fields. For the California site, the applications were made beginning in mid July 1997 for the foliage sampling and early July 1998 for the soil sampling. For the Florida site, the applications were made in mid November 1997 for the foliage sampling. Vydate®L was applied twice at each site using a broadcast boom sprayer at an application rate of 1.0 lb ai per acre in 50 gallons per acre of final volume. The data from leaf punches and soil samples after the second treatment were used to characterize concentration of oxamyl on the treated crop or soil and the rate of dissipation. Numerous rainfall events occurred during the study at the Florida site. During the study from Nov. 13, 1997 - Dec. 23, 1997, 14.40 inches of precipitation fell at the Florida site, while the 10-year average precipitation amounts were 2.36 inches in Nov. and 2.82 inches in December. Only one rain event occurred at the California site (0.05 inches), no precipitation was reported at the California site for the soil residue study.

The average residues immediately after the second application were 1.600 g/cm^2 at the Florida site and 2.780 g/cm^2 at the California site. After 14 days, the residues declined to 0.004 g/cm^2 at the Florida site and 0.047 g/cm^2 at the California site. Since it was not stated whether the DFR residues provided by the registrant were corrected, HED corrected the residues based on the field recovery and used the corrected residues for regression analysis. HED's calculated R^2 values and predicted half-lives were different from the values reported by the registrant. The registrant reported the half-life of oxamyl as 1.6 days for the Florida DFR site, 0.7 days for the California DFR site, and 5.3 days for the Soil residue site. HED calculated a half-life of 1.6 days with R^2 of 0.99 for the Florida DFR site, a half-life of 5.8 days with R^2 of 0.67 for the California DFR site, and a half-life of 6.8 days with R^2 of 0.80 for the California Soil residue site. At the Florida site, the DFR residues were less than the limit of quantitation (LOQ) of 0.001 µg/cm^2 after Day 14; therefore, data on Day 21, 28, and 35 were removed from regression analysis for this site.

Since the maximum application rate for tomatoes is 2 lbs ai/acre for soil and only 1 lb ai/acre was applied immediately before the sampling had begun, the predicted soil data DFR values were doubled. Results from the HED regression analysis are presented in Table 12 of this report.

Table 12. Predicted Tomato Foliar and Soil Dissipation Values for Oxamyl, Based on Log Transformed Data.

DFR and Soil Dissipation (g/cm^2)										
Site	0 DAT	1 DAT	2 DAT	3 DAT	4 DAT	5 DAT	6 DAT	7 DAT	R^2	Slope ($t_{½}$ days)[a]
Florida	1.85	1.21	0.79	0.51	0.34	0.22	0.14	0.094	0.99	-0.425 (1.62)
California (foliar)	0.56	0.50	0.45	0.40	0.35	0.31	0.28	0.25	0.67	-0.119 (5.84)
California (soil)	15.8	14.2	12.8	11.6	10.5	9.5	8.5	7.7	0.80	-0.102 (6.79)

a $t_{½}$ is the calculated half-life of oxamyl at the Florida site are from 0 DAT to 14 DAT and the half-life of Oxamyl at the California site are from 0 DAT to 35 DAT.

The dislodgeable foliar and soil residue study completed in support of the regulatory requirements contained the following omissions and flaws with respect to Series 875 - Group B guidelines. However, the data collected in this study are of sufficient scientific quality.

- a storage stability study was not presented and is recommended due to the short half life of the pesticide and the poor field recovery for some of the samples.

- the results of the control samples were not reported in the study, so it could not be identified whether any chemical interference took place in the control samples.

- the application rate on soil was not at the highest label rate permitted of 2 lbs ai/A. HED doubled the predicted values from the regression analysis to correct for this.

- since the field recovery was less than 90 percent, the DFR data should have been corrected based on the field recovery percentage.

- only two DFR sites and only one soil residue site were addressed, but Series 875 - Group B guidelines recommends three sites for foliage and soil.

The field fortification recoveries should take into account any storage stability problems. The residue data were corrected for recoveries by HED.   HED recognizes that two sites are not as representative of the entire country as the three sites required by the guidelines. The rest of the omissions or flaws with respect to the Series 875 - Group B guidelines are not considered to significantly affect the outcome of the data.

For the exposure from tomato foliage, the assessment uses a transfer coefficient (Tc) for tomatoes of 10,000 cm^2/hr for activities such as hand harvesting, staking, tying, scouting and irrigating[6]. The study was conducted at two sites, one in Florida and one in California. The R^2 value for the Florida site (0.67) was lower that the California site (0.99). The dissipation rates and actual initial residues were very different for both sites. The dissipation rates were determined from the regression analysis to be 43 percent per day for the Florida site and 12 percent per day for the California site. While the initial residues for the California site was almost twice the Florida site, the residues drop dramatically from day 0 to day 1. The dissipation rate for the California site from day 0 to day 1 was 66 percent, much higher than the average dissipation rate of 12 percent per day. The DFR data were derived by correcting the raw data for recoveries and then running a regression analysis on the data. The predicted DFR data from the regression analysis were then used to obtain the dose for each day. The daily DFR, dose and MOE values are presented in Table 13.

Table 13. Oxamyl Surrogate Postapplication Assessment for Tomatoes (foliage).

DAT[a]	DFR (µg/cm^2)[b]		Dermal Dose (mg/kg/day)[c]		MOE[d]	
	FL	CA	FL	CA	FL	CA
0	1.8	0.56	2.1	0.64	24	78
3	0.52	0.40	0.59	0.45	85	110
4	0.34	NA	0.38	NA	130	NA

Footnotes

NA = Not applicable

[a] DAT is “days after treatment”

[b] Predicted DFR was obtained through study data of the insecticide residues on tomato foliage.[9]

[c] Dose = DFR (g/cm^2) x Transfer coefficient (10,000 cm^2/hr) x Conversion factor (1mg/1000 g) x Dermal absorption (1) x Hrs worked per day   (8 hrs) / Body weight (70 kg)

[d] MOE = NOAEL (mg/kg/day) / Dermal dose (mg/kg/day). Where: NOAEL is 50 mg/kg/day.

For tomato foliage, the calculated MOE exceeded the target MOE of 100 on day 4 for the Florida site and day 3 for the California site.

The study on soil residue was conducted in California about a year after the California foliage study. The soil residue data were derived by correcting the raw data for recoveries and then running a regression analysis on the data. The dissipation was determined from the regression analysis to be 10 percent per day for the California site. The predicted soil residue data from the regression analysis were then used to obtain the dose for each day. The study application rate was 1 lb ai/acre.

Data was not submitted to determine soil transfer coefficients. An exposure study done in conjunction with soil residue data collection to determine the transfer rate of the pesticide from the treated soil to the worker may be required pending the outcome of discussions with the registrant and others on the postapplication risk and risk mitigation.

Remaining Crops

The days after treatment when the calculated MOE was above the target MOE for crops other than tomatoes, cucumbers, and citrus were calculated using the DFR data as surrogate data. The citrus residue data (MRID 44686901) were used to assess exposure to foliage from the tree crops (pears, apples, and non-bearing trees). The tomato residue data (MRID 44704801) were used for assessing exposure to foliage from the high transfer coefficient crops (Tc = 10,000 cm^2/hr). The cucumber residue data (MRID 44686902) were used for assessing exposure to foliage from the medium to low transfer coefficient crops (Tc 4,000 cm^2/hr). The DFR values from the three submitted studies were adjusted proportionately to reflect remaining crops application rates. The new DFR values are calculated as follows:

$$Adjusted\ DFR\ (\ g/cm^2) = \frac{Study\ DFR\ (\ g/cm^2)\ x\ crop\ application\ rate\ (lbsai/A)}{study\ application\ rate\ (lbsai/A)}$$

Ginger, cucurbits, peanuts, cotton, peppers, and eggplant crops, have the same transfer coefficient (4,000 cm^2/hr, from activities such as hand harvesting, staking, tying, scouting irrigating), application rate (1 lb ai/acre) and thus the day after treatment where the calculated MOE was above the target MOE as cucumber foliage and will not be reassessed. White potatoes, garlic, and onion crops, have the same transfer coefficient (10,000 cm^2/hr, from activities such as hand harvesting and digging), application rate (1 lb ai/acre) and thus the day after treatment where the calculated MOE was above the target MOE as tomato foliage and will not be reassessed. For crops that have no foliar uses, mint, soybeans, carrots, tobacco, sweet potatoes, and bananas, the day when the calculated MOE is greater than the target MOE cannot be calculated. The DFRs and MOE values from foliage exposure from crops not already mentioned above are presented in Table 14.

Table 14. Surrogate Oxamyl Postapplication Assessment for Remaining Crops Using DFR Study Data.

Maximum Label Foliar Application Rate (lbs ai/acre)	Transfer Coefficient[a] and Activity	DFR Surrogate Data Source	Crop	DAT[b]	DFR[c]		MOE[d]	
					FL/GA[e]	CA	FL/GA[e]	CA
2	10,000 Hand harvest and prune	citrus	Pear, Apple and Non-Bearing Fruit Trees	0	2.1	1.5	21	27
				5	0.4	1.0	110	44
				16	NA	0.43	NA	103
1	2,500 hand harvest	cucumber	celery	0	(4.1)	3.2	43	55
				1	(0.87)	2.4	200	73
				3	NA	1.4	NA	130
2	2,500 hand harvest	cucumber	pineapples	0	(8.2)	6.4	21	28
				1	(1.7)	4.8	100	37
				5	NA	1.6	NA	110
0.5	10,000 digging and hand harvesting	tomato	yams	0	0.92	(1.8)	47	25
				2	0.4	0.23	110	200

<u>**Footnotes**</u>
NA = Not applicable
[a] Transfer Coefficients from Science Advisory Council on Exposure Policy 3.[6]
[b] DAT is "days after treatment"
[c] Predicted DFR was obtained through study data of the insecticide residues on the foliage of citrus trees (MRID 44686901) for pears, apples and non-bearing fruit trees, through study data of the insecticide residues on cucumbers (44686902) for celery and pineapples, and through study data of the insecticide residues on tomatoes (44704801) for yams.[7,8,9] DFR values were adjusted proportionately to reflect different application rates. The adjusted DFR = (study DFR X crop application rate)/study application rate. The DFR data in parenthesis were actual data.
[d] MOE = NOAEL (mg/kg/day) / Dermal dose (mg/kg/day).
[e] The studies with Florida as its test site were used to assess yams, pears, apples and non-bearing fruit trees. The study with Georgia as its test site was used to assess celery and pineapples.

For ginger, cucurbits, peanuts, cotton, peppers, and eggplant foliage, the calculated MOE exceeded the target MOE of 100 on day 1 for the Georgia site and day 4 for the California site. For pear, apple and non-bearing fruit tree foliage, the calculated MOE exceeded the target MOE of 100 on day 5 for the Florida site and day 16 for the California site. For celery foliage, the calculated MOE exceeded the target MOE of 100 on day 1 for the Georgia site and day 3 for the California site. For pineapple foliage, the calculated MOE exceeded the target MOE of 100 on day 1 for the Georgia site and day 5 for the California site. For white potatoes, garlic and onion foliage, the calculated MOE exceeded the target MOE of 100 on day 3 for the California site and day 4 for the Florida site. For yams, the calculated MOE exceeded the target MOE of 100 on day 2 for both the Florida and the California sites.

Data Needs

An exposure study done in conjunction with soil residue data collection to determine the transfer rate of the pesticide from the treated soil to the worker may be required pending the outcome of discussions with the registrant and others on the postapplication risk and risk mitigation.

Summary of Risk Concerns for Post-Application Workers.

The resulting postapplication assessments indicate that the MOEs equal or exceed 100 on the day specified for the following crops, according to the site and activity mentioned. See Table 15 for summary.

Table 15. Days After Treatment.

Crop	Activity and Transfer Coefficient (cm^2/hr)	Application Rate (lbs ai/A)	Day after Application When MOE 100[a]	
			FL/GA	CA
Citrus Trees	10,000 - hand harvesting and pruning	1	3	7
Pear and Apple	10,000 - hand harvesting and pruning	2	5	16
Non-bearing Fruit Trees	10,000 - transplanting, pruning, and hand harvesting	2	5	16
Cucumbers, ginger, cucurbits, peanuts, cotton, peppers, and eggplant	4,000 hand harvesting, scouting, irrigating, staking/tying	1	1	4
Celery	2,500 - hand harvesting	1	1	3
Pineapples	2,500 - hand harvesting	2	1	5
Tomatoes	10,000 - hand harvesting, staking/tying, irrigating	1	4	3
Yams	10,000 - hand harvesting and digging	0.5	2	2
White Potatoes, garlic, and onions	10,000 - hand harvesting and digging	1	4	3

Footnote
[a] Day after application when the calculated MOE is greater than the target MOE of 100. The target MOE of 100 is includes a 10 uncertainty factor for interspecies variation and a 10 uncertainty factor for intraspecies variation.

References

1) Oxamyl labels. Reg. Numbers: 352-372, 352-400, and 352-532.

2) Oxamyl LUIS Table for Exposure Assessors. Report Run Date: November 6, 1998.

3) Reddy, Guruva. Oxamyl - Report of the Hazard Identification Assessment Review Committee. August 31, 1999.

4) HED Science Advisory Council for Exposure, Policy 007, *Use of Values from the PHED Surrogate Table and Chemical-Specific Data*. Health Effects Division, Office of Pesticide Programs, January 1999.

5) PHED Surrogate Exposure Guide. Health Effects Division, Office of Pesticide Program, August 1998.

6) HED Science Advisory Council for Exposure, Policy 003. *Agricultural Default Transfer Coefficients*. Health Effects Division, Office of Pesticide Programs, May 7, 1998.

7) *"Dissipation of Dislodgeable Foliar Residues of Oxamyl From Cucumbers Following Application of Vydate®L Insecticide in the U.S.A. - Season 1997."*; MRID 446869-02. October 21, 1998.

8) *"Dissipation of Dislodgeable Foliar Residues of Oxamyl From Citrus Following Application of Vydate® L Insecticide in the U.S.A - Season 1997"*; MRID 446869-01. October 20, 1998.

9) *"Dissipation of Dislodgeable Foliar and Soil Residues of Oxamyl Following Application of Vydate®L Insecticide to Tomatoes in the USA- Season 1997 and 1998."*; MRID 447048-01. October 26, 1998.

10) HED Science Advisory Council for Exposure, Policy 009. *Agricultural Default Transfer Coefficients*. Health Effects Division, Office of Pesticide Programs, April 1, 1999.

Appendix 1
Raw Data From Dissipation Studies

Residue Dissipation Study on Tomatoes in California and Florida.

Name of Trial:	Oxamyl in FL	Oxamyl in CA	Oxamyl Soil Residue in CA
Days after Application	**Residue Concentration (g/cm^2)**		
0	2.12	4.21	18.48
0	1.69	3.29	18.09
0	2.29	3.10	6.66
1	1.14	1.40	14.70
1	1.11	1.03	8.98
1	1.18	1.13	16.52
2	0.7393	0.2414	6.27
2	0.8473	0.3620	9.55
2	0.8867	0.3061	6.79
3	0.5691	0.1435	4.94
3	0.4459	0.1944	4.35
3	0.4624	0.2693	3.10
7	0.1334	0.0775	3.40
7	0.0673	0.0673	3.81
7	0.0762	0.0661	2.70
14	0.0064	0.0394	1.22
14	0.0051	0.0279	1.18
14	0.0038	0.1118	0.4357
21		0.0267	0.3392
21		0.0178	0.4370
21		0.0483	0.6987
28		0.0102	0.2998
28		0.0292	0.6097
28		0.0406	0.3836
35		0.0089	0.5246
35		0.0152	0.7368
35		0.0597	0.3404

Residue Dissipation Study on Cucumbers in California and Georgia

Name of Trial:	Oxamyl in CA	Oxamyl in GA
Days after Application	Residue Concentration (g/cm^2)	
0	3.68	3.96
0	3.83	4.14
0	4.05	4.23
1	4.07	0.8933
1	2.77	0.9460
1	3.43	0.7687
2	2.91	0.2317
2	2.85	0.2141
2	2.75	0.2229
3	1.20	0.0860
3	1.46	0.0807
3	1.40	0.1106
7	0.3536	0.0105
7	0.2678	0.0053
7	0.2665	0.0088
14	0.0308	0.0018
14	0.0256	0.0053
14	0.0167	0.0035
21	0.0064	
21	0.0051	
21	0.0038	
28	0.0038	
28	0.0064	
28	0.0051	

Residue Dissipation on Citrus Trees in Florida and California

Name of Trial:	Oxamyl in FL	Oxamyl in CA
Days after Application	Residue Concentration (g/cm^2)	
0	2.17	2.30
0	1.79	1.80
0	2.36	2.06
1	1.65	0.3251
1	1.19	0.5322
1	1.48	0.4408
2	0.4544	0.4952
2	0.5442	0.5449
2	0.4128	0.6375
3	0.2466	0.5993
3	0.3404	0.5692
3	0.2493	0.4720
7	0.0094	0.1481
7	0.0911	0.4420
7	0.0241	0.2221
14	0.0094	0.2233
14	0.0027	0.3529
14	0.0094	0.2904
21	0.0007	0.0798
21	0.0040	0.1944
21	0.0040	0.1840
28	0.0009	0.0625
28	0.0067	0.1735
28	0.0007	0.0659
35	0.0007	0.0243
35	0.0007	0.0740
35	0.0007	0.0740